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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/562,954               | 12/30/2005  | Janel Birk           | 17957B US PCT (HEA) | 8688             |
| 51957                    | 7590        | 05/20/2010           | EXAMINER            |                  |
| ALLERGAN, INC.           |             |                      | FISHER, ELANA BETH  |                  |
| 2525 DUPONT DRIVE, T2-7H |             |                      | ART UNIT            | PAPER NUMBER     |
| IRVINE, CA 92612-1599    |             |                      | 3733                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/562,954             | BIRK ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | ELANA B. FISHER        | 3733                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 March 2010.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-29, 38 and 66-81 is/are pending in the application.

4a) Of the above claim(s) 81 is/are withdrawn from consideration.

5) Claim(s) 66-80 is/are allowed.

6) Claim(s) 1-29 and 38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01/22/2010.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-11, 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Conlon et al. (U.S. Publication 2004/0254537).

Conlon et al. disclose a method of securing a device (28) to bodily tissue comprising: providing a device having an associated attaching means (18), wherein the attaching means comprises a housing (20) surrounding the perimeter of the device and comprises a plurality of notches or openings (36). The notches or openings comprise a fastening means (30) pivotally attached to the housing. The method additionally comprises positioning the device (28) and attaching means (18) on the bodily tissue (FIG 12), covering the device and attaching means with a delivery system (FIG 12); and activating the delivery system such that the fastening means (30) are pivotally rotated from a first position to a second position to secure the device in bodily tissue (FIG 13; Paragraph [0062]). The pivotal rotation is accommodated by the notches or openings (36), and wherein the fastening means (30) are locked into the second position by a locking tab (22a). The method further comprises removing the delivery system from the secured device and attaching means (Paragraph [0063]).

The housing (20) is integral & detachable with the body (22) of the device and surrounds the outside of the device (28), such that the device is securely contained within the housing after said activating step (FIG 3). Additionally, the fastening means (30) is a staple that is shaped substantially in the shape of a hexagon with two contiguous sides of the hexagon omitted (FIG 4). A first leg (32) of the staple (30) is pivotally attached to the housing (FIG 2) and a second leg (30c) of the staple punctures the bodily tissue, while maintaining its shape, when pivotally rotating, such that the bodily tissue is secured between the second leg of the staple and the device (FIG 12).

The plurality of notches or openings (36) is spaced equidistant around the housing (FIG 2). The delivery system (FIG 10) comprises a cover (46), a plunger (48), a slide pusher (66) and a slide assembly (68), wherein the slide assembly comprises beams (70), wherein the beams are spaced so as to line up with the notches or openings on the housing of the attaching means. The plunger (48) is activated via a pencil grip system, a palm grip system or a pistol grip system (66; FIG 10). Additionally, the slide assembly (68) moves towards the housing and device when the plunger is activated (FIG 11; FIG 12), and the beams (76a, 76b) push against the fastening means when the plunger is activated, causing the fastening means to pivotally rotate (FIG 12).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al. (U.S. Publication 2004/0254537).

Conlon et al. disclose a method and attaching means according to claim 4 above, however fail to disclose the material that comprises the staple (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the staple (30) is comprised of one or more of: stainless steel, Elgiloy TM, cobalt-chromium alloy, or nickel-titanium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

5. Claims 17-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlon et al. (U.S. Publication 2004/0254537) in view of Yoon (U.S. Patent 5,540,648).

Conlon et al. disclose an attaching means (18), wherein the attaching means comprises a housing (20) surrounding the perimeter of the device and comprises a plurality of notches or openings (36) space equidistant from one another. The notches or openings comprise a fastening means (30) pivotally attached to the housing. The fastening means (30) may be rotated from a first position to a second position to secure the device in bodily tissue (FIG 13; Paragraph [0062]). The attaching means further comprises a locking tab (22a). The housing (20) is integral and detachable from the attaching means. Additionally, the fastening means (30) is a staple that is shaped substantially in the shape of a hexagon with two contiguous sides of the hexagon omitted (FIG 4). A first leg (32) of the staple (30) is pivotally attached to the housing (FIG 2) and a second leg (30c) of the staple punctures the bodily tissue, while maintaining its shape,

when pivotally rotating, such that the bodily tissue is secured between the second leg of the staple and the device (FIG 12). The attaching means further comprises a rotatable disc (126) for rotating the fastening means (30) from the first position to the second position (FIG 21).

However, Conlon et al. fail to disclose the material that comprises the staple (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the staple (30) is comprised of one or more of: stainless steel, Elgiloy TM, cobalt-chromium alloy, or nickel-titanium alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Additionally, Conlon et al. disclose that each fastener (30) has a sharp tip (30d) for piercing tissue. In the first position (FIG 3) the sharp tips of the fasteners are located above a bottom surface of the housing. In the second position (FIG 13) the fasteners (30) rotate so that the sharp tips pass through the tissue below the housing. However, Conlon et al. fail to disclose that the sharp tips nest against the bottom surface of the housing. Yoon discloses attaching means (FIG 1) comprising a plurality of fasteners (26) that are rotated through a housing from a first position (FIG 3) with sharp tips (28) located above a bottom surface of the housing to a second position (FIG 4) with the sharp tips nested against the bottom surface of the housing (FIG 4). It therefore would have been obvious to one skilled in the art to modify the attaching means taught by Conlon et al. by having the sharp tips of the fastening means nest against the bottom surface of the housing in the

second position, as is taught by Yoon, because that positioning of the fastening means successfully captures tissue between the fastening means and the housing which securely anchors the attaching means in place (Yoon; Column 5, lines 66-67 and Column 6, lines 1-2).

***Allowable Subject Matter***

6. Claims 66-79 are allowed.
7. Claim 80 is allowable. The restriction requirement as set forth in the Office action mailed on September 30, 2010, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claim 80, directed to the non-elected invention is no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claim 81, directed to a non-elected invention is withdrawn from consideration because the claim is dependent upon rejected claim 1 and requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Response to Arguments***

8. Applicant's arguments filed March 16, 2010 have been fully considered but they are not persuasive.

With regards to applicant's arguments, examiner respectfully disagrees.

Specifically examiner disagrees with applicant's arguments regarding claim 1. Applicant argues that element 22a taught by Conlon et al. is not a locking tab. Examiner maintains that element 22a locks the fasteners in the correct longitudinal alignment, thereby assuring that the fasteners are not directed sideways during their rotational movement.

Accordingly, the rejection over Conlon et al. is maintained.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733